DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 5,2015

Wieland Dental + Technik Gmbh & Co. Kg
c/o Ms. Donna Marie Hartnett
Director QA/Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K142233
Trade/Device Name: Zenostar Mo, Zenostar T, Zenostar VisualiZr
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: November 26, 2014
Received: December 5, 2014

Dear Ms. Hartnett,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin Keith
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142233

Device Name: **Zenostar MO, Zenostar T, Zenostar VisualiZr**

Indications For Use:

Zenostar MO and Zenostar T consist of machinable zirconia discs for the preparation of full ceramic crowns, onlays and bridges (anterior and molar).

Zenostar VisualiZr is for the temporary dyeing of Zenostar Color Zr solutions according to the Instructions for Use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

WIELAND DENTAL™
A MEMBER OF THE IVOCLAR VIVADENT GROUP

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, AG
Benderertrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: January 2, 2015

Proprietary Name: **Zenostar MO, Zenostar T, Zenostar VisualiZr**

Classification Name: Powder, Porcelain (872.6660)
(Classification Code EIH)

Predicate Device: IPS e.max ZirCAD (K051705) by Ivoclar Vivadent, AG (Liechtenstein) and Zenotec Zr Bridge, Zenostar Zr Translucent, Zenotec Color Zr, Zenostar Color Zr, by Wieland Dental (K112710).

Device Description: Zenostar MO and Zenostar T are pre-sintered Zirconia discs with 98.5mm width and various thickness for use in the fabrication of dental prosthesis through the CAD/CAM milling technology. After milling, they are to be sintered at a high temperature to its full density, in order to achieve its expected physical properties. In addition, visualizer coloring liquid concentrates for dyeing Zenostar Color Zr (K11270) Solutions.

Indications for Use:

Zenostar MO and Zenostar T consist of machinable zirconia discs for the preparation of full ceramic crowns, onlays and bridges (anterior and molar). Zenostar VisualiZr is for the temporary dyeing of Zenostar Color Zr solutions according to the Instructions for Use.

Intended Use:

Zenostar MO (Medium Opacity) are milling discs intended for the fabrication of crown frameworks and multi-unit bridge frameworks for use as dental restorations.

Zenostar T (Translucent) are milling blanks intended for making single-tooth and multi-unit restorations for use as dental restorations. Depending on the indication, frameworks or monolithic (full contour) restorations can also be made

Zenostar VisualiZr is for the temporary dyeing of Zenostar Color Zr solutions according to the Instructions for Use.

Comparison to Predicate: The predicate device to which Zenostar MO has been compared is IPS e.max ZirCAD (K051705) and Zenostar T and Zenostar VisualiZr have been compared to the predicate Zenotec Zr Bridge, Zenostar Zr Translucent, Zenotec Color Zr, Zenostar Color Zr, by Wieland Dental (K112710). For this application, Zenostar MO, Zenostar T have been compared to its predicate with regard to chemical composition, performance data and

indications for use. The comparison shows that Zenostar MO, Zenostar T are substantially equivalent to the predicate device. Zenostar VisualiZr is an accessory only and bears no effects on the device or its comparison to the predicate. The predicate device e.max ZirCAD is available in 1 shade and 1 block size. The subject device is available in 5-7 shares and 7 different disc thicknesses.

The intended use of both Zenostar MO and T are the same. They are used as restorative materials for crowns and bridges. However aesthetic criteria which have to be fulfilled vary depending on the esthetic requirements in the mouth. The availability of Zenostar in two grades of translucency allows the product to be selected which is best suited to the esthetic situation. The physical properties of both products are the same and both MO and T could be used for the identical indications, however due to the esthetic consideration we describe the indications which are most appropriate for each version. The medium opacity material “MO” is most appropriate used as a framework material, which will be covered with a more esthetic layering ceramic. The translucent material “T” is appropriate for monolithic solutions due to the good translucency.

Technological Characteristics: The device design, i.e. delivery form, and intended use of Zenostar MO, Zenostar T and the predicate device are the same. Zenostar VisualiZr bears no effects on the technological characteristics of the device. The predicate device e.max ZirCAD was delivered in block shape for use in the Sirona In-Lab dry CAD/CAM System. The subject device is sold in 98.5mm disc shape for use in the Wieland wet CAM milling system.

Testing Summary: The device has been designed and tested in accordance with ISO 6872:2008 Dentistry: Ceramic Materials for Flexural Strength, Chemical Solubility, Co-efficient of thermal expansion and Radioactivity. The test results are equivalent to those of the predicate device. Biocompatibility data are not submitted because the ingredients of the subject device and the predicate are equivalent. For the VisualiZr Colors, the liquid burns out almost completely during sintering. Any remaining molecules are bound in the molecular structure of the sintered restoration.

CONCLUSION: The above data and analysis demonstrates that Zenostar MO, Zenostar T and Zenostar VisualiZr are substantially equivalent to the predicate device.